

REMARKS

Summary

The present invention is specifically directed towards a method of treating acute and chronic myeloid leukemia (AML & CML) and lymphoid leukemia, using a composition that is either a synergistic combination of chlorogenic acid (CA) and 3-o-p-Coumaryl quinic acid (PCQ) in the ratio 1:1 to 1:10, or a particular composition that is essentially CA, or essentially, PCQ.

Status of the Claims

Claims 1-7 were provisionally rejected for non-statutory Double Patenting, in view of claims 5-6 of co-pending Application No. 10/338,688.

Sole independent claim 1 is proposed to be amended to emphasize the disclosed fact of a synergistic combination of CA and PCQ. Claims 8 and 9 have been rewritten to be in independent form. Claims 11 and 14 now depend on claim 8 and claims 12 and 15 now depend upon claim 9.

Dependent claims 5, 11, 12, 14 and 15 have been amended to obviate informalities. Claim 18 is cancelled. Claims 1-17 now remain pending in the application, with Claims 1, 8 and 9 being independent. This application claims benefit to provisional application number 60/393,750, which results in an effective U.S. filing date of July 8, 2002.

The initial rejections of all claims after the Request for Continued Examination, were withdrawn in view of 35 USC§ 103 (c).

Requested Action

Entry of this amendment, entry of the attached Fifth Terminal Disclaimer, withdrawal of the initial rejections and a Notice of Allowance are requested.

Response to the Substantive Rejection

Claims 1, 8 and 9 reflect the disclosed fact that betel leaf extract contains a large number of compounds along with chlorogenic acid (CA) and 3-o-p-Coumaryl quinic acid (PCQ). The inventors expended considerable amounts of time and effort in selectively identifying the two compounds namely chlorogenic acid (CA) and 3-o-p-Coumaryl quinic acid (PCQ), from a pool of compounds present in Betel leaf extract, in a specific ratio showing an anti-leukemic and anti-tumor activity. Although inhibition of tumor promotion has been attributed to chlorogenic acid (CA), anti-tumor activity on established tumors including anti-leukemic activity has been particularly taught and distinctly claimed for the first time in the present invention.

Only the present specification identifies and presents positive data supporting the synergistic combination of the particular components, chlorogenic acid (CA) and 3-o-p-Coumaryl quinic acid (PCQ), showing increased activity in treatment of AML, CML and lymphoid leukemia.

The co-pending Application No. 10/338,688, and claims 5 and 6 thereof, does not specifically recite any effective ratio of chlorogenic acid (CA) and 3-o-p-Coumaryl quinic acid (PCQ) at which any effective composition should be administered to obtain the percentage growth inhibition of promonocyte cells, erythroleukemia cells or CML's leukemia cells as taught and claimed in the present invention .

The provisional obviousness-type Double Patenting rejection is predicated upon pending claims 5 and 6 of Application No. 10/338,688, which was published as Bandyopadhyay et al. (USP Appln. Pub. No. 2003/0229140) ['140 Publication].

The '140 Publication is by the same five inventors named herein; claims benefit to the same provisional application number 60/393,750 claimed herein which results in the same effective U.S. filing date of July 8, 2002; and was not published until December 11, 2003.

Attached is a Fifth Terminal Disclaimer, based upon Application No. 10/338,688.

The Examiner previously had indicated that the four Terminal Disclaimers filed with the January 3, 2007 Amendment were effective to eliminate any possibility of any continued "obviousness type double patenting" rejections.

Favorable reconsideration, withdrawal of the objections and rejections set forth in the initial non-final Office Action, and an early Notice of Allowance are requested.

Any additional fee required to render this response timely may be charged to Deposit Acct. No. 06-1205. All correspondence should continue to be directed to the below-listed address.

If questions remain prior to a Notice of Allowance, the Examiner is urged to telephone the undersigned attorney of record in our Washington, DC, at (202) 530-1010.

Respectfully submitted,

/Warren E. Olsen/
Warren E. Olsen (Reg. No. 27,290)

Attachment: Fifth Terminal Disclaimer

FITZPATRICK, CELLA, HARPER & SCINTO
Customer No.: 05514
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200